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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,710	05/16/2001	Franciscus Bernardus Gemma Benneker	POT-010US3	9651

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HOWREY & SIMON
P.O. BOX 34
1299 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2402

EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,710

Applicant(s)

BENNEKER ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 24, 25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4. 6) ☐ Other: _____

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DETAILED ACTION

1. This application is a divisional of SN 09/200,743. Claims 1-23 have been canceled. Claims 24-29 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 27-29 are rejected under 35 U.S.C. 102(b) or 102(e) as being anticipated by Barnes US 4,721,723 (cited on 1449) or Ward et al. US 5,872,132.

Claims 27-29 are drawn to product by process. The hydrochloride salt of paroxetine prepared by the process is evidenced to be crystallized from aqueous solvent or organic solvent such as isopropanol (see p. 7 specification and examples 5-6). The products are thus, paroxetine hydrochloride hemihydrate or isopropanol solvate which are anticipated by Barnes et al. '723, col.7, examples 2-3 or col. 9-10, example 8, i.e. Ward '132, see col. 4 lines 55-57 and col. 7-8 examples 1-3. The product by process claims are products which are evidenced by Barnes or Ward that such products are substantially identical to those prepared and disclosed by Barnes or Ward. Applicants bear the burden to come forward with evidence establishing an unobvious difference between the claimed product and the prior art in product by process claims because of their peculiar nature (MPEP 2113).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 24-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Stemp et al. EP 190,496 (cited on 1449) in view of Barnes et al. US 4,721,723.

Determination of the scope and content of the prior art (MPEP §2141.01)

Stemp et al. '496 disclosed process of making paroxetine hydrochloride from paroxetine organic acid salt (see pages 51-52). The variation of available pharmaceutically acceptable salts including methanesulphonic acid were provided on page 3.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Stemp et al. '496 disclosed all the elements of the claims **except** an example employing the generically taught methanesulphonic acid was not exemplified.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the Stemp '496 reference is in possession of the instant claimed process **because** the reference generically disclosed the starting material and process of making with exemplification of one of such process. Especially, in the instant art, paroxetine hydrochloride has been conventionally prepared from other organic salt such as disclosed by Barnes (col. 7 examples 2-3, col. 9-10 example 8), therefore, one skilled in the art would have the expectation that the routine pharmaceutically acceptable salts as disclosed by Stemp '496 are conventional and would be successful to carry out the conventional conversion routinely done in this field.

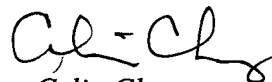
4. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 26 employed the particular solvent ethylacetate which was not disclosed in the prior art nor any motivation for suggesting this specific solvent.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Celia Chang
Primary Examiner
Art Unit 1625

OACS/Chang
Sept. 5, 2002